Final Report:

Prosthetics & Orthotics Manufacturing Initiative (POMI)

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14. ABSTRACT
The Prosthetics & Orthotics Manufacturing Initiative (POMI) was an ambitious program designed to give tools to the practitioners providing patient care to the nation?s wounded warriors. The intent was to improve the design and manufacture of custom composite sockets. This was expected to improve the sockets produced, while at the same time reducing cost and labor input required from practitioners, allowing them to focus limited resources on patient care, including emerging best practices for the rehabilitation of those suffering from limb loss.

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Executive Summary

The Prosthetics & Orthotics Manufacturing Initiative (POMI) was an ambitious program designed to give tools to the practitioners providing patient care to the nation's wounded warriors. The intent was to improve the design and manufacture of custom composite sockets. This was expected to improve the sockets produced, while at the same time reducing cost and labor input required from practitioners, allowing them to focus limited resources on patient care, including emerging best practices for the rehabilitation of those suffering from limb loss.

Five major activities were pursued. They will be referred to by the following names and numbers throughout this report. Task 1: Reconfigurable Sockets pursued two competing technologies to allow composite sockets to be adjusted after they were fabricated. The goal was to allow sockets to be changed to adjust to changes in the patient's anatomy, thereby reducing the number of sockets that needed to be fabricated. Task 2: Medical Imaging and Modeling pursued a novel paradigm for designing sockets with full information of the patient's anatomy, gathered by Magnetic Resonance Imaging (MRI). Using the information from the MRI, and applying stress-strain properties generalized for each tissue type, this task sought to allow prediction of the loading paths for a given socket design, which would allow an assessment of the design's comfort prior to fabrication, and would allow great flexibility in implementing novel designs. Task 3: 3-D Pressure Mapping focused on implementing a pressure mapping system which could be deformed over the patient's residual limb, allowing for full, high-resolution information for the entire limb, informing design decisions. Task 4: Automated Fabrication translated a well-established composites manufacturing technique, braiding, to the manufacture of composite sockets. Task 6: Active Cooling Liner demonstrated a new system for providing cooling to the residual limb, to combat overheating issues, increase comfort, and aid in skin care. This technology had been previously commercialized for full body use, and it's efficacy for the prosthetic environment was demonstrated.

These various activities met with varying levels of success and transition. One of the two competing technologies pursued in Task 1: Reconfigurable Sockets was determined to have promise in allowing sockets to be adjusted after manufacture. The most likely configuration involves placing shape-memory foams, which are activated with heat, between layers of carbon fabric during socket fabrication. Prototypes were developed, and delivered to Walter Reed Army Medical Center (WRAMC), The Center for the Intrepid (CFI) at Brooks Army Medical Center (BAMC), and the Navy Medical Center at San Diego (NMCSD), and were well received. Task 2: Medical Imaging and Modeling encountered numerous difficulties in verifying the results of the finite element analysis (FEA), and were unable to overcome these difficulties. Task 3: 3-D Pressure Mapping was successful in developing a system which took pressure maps of the residual limb. There were issues in calibrating the system, and the temporal resolution was insufficient to measure events associated with activities such as walking. The system was commercially launched, and a small population of first adopters has purchased it. Since, the system has been extended into use for orthotics and measuring the pressure wave associated with blast events, for helping to diagnose traumatic brain injuries. Task 4: Automated Fabrication succeeded in proving out the use of braiding for production of prosthetic sockets. Using 3-year average numbers for the cost of a prosthetic socket from a central fabrication facility, braided sockets save 34% of the cost of a traditional socket, offer approximately twice the strength-to-weight ratio, and require roughly half of the skilled labor input to create. As a result, two central fabrication facilities invested in the technology, purchasing, installing, and operating braiding units to supply sockets to active, veteran, Paralympian, and civilian populations. Task 6: Active Cooling Liner demonstrated that the liquid carbon dioxide-based system could provide cooling through the thermal resistances of the viscoelastic liner now commonly worn by prosthetic patients. This is the only known design capable of preventing overheating in the socket, and this concept may be suitable for commercialization efforts in the future.

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Introduction

The realities of the current engagement are that more warriors are surviving injuries and living with amputations. The capabilities of our care systems are strained by increased demands, not only in terms of sheer numbers, but also in the functional level that our young warriors want to be restored to. While the current care systems are providing excellent care, this project focused on opportunities to improve processing and manufacturing of prosthetic systems to increase durability and comfort, and on giving medical personnel tools to aid in the care of our most deserving. This will allow them to focus limited resources on patient care.

Background

The asymmetric nature of the conflicts in Iraq and Afghanistan has resulted in a high number of traumatic injuries. In addition, major improvements to battlefield medical logistics have resulted in greatly increased survival rates. These brave men and women returning from combat are facing multiple challenges in returning to life, either as a veteran or as part of the active military.

At the same time, these young warriors are demanding restoration to higher and higher functional levels. This is enabled by the advance of prosthetics technology, certainly, but the commitment of resources required to achieve it has increased as the complexity of the technology has increased.

In order to allow increased focus on patient care, and the restoration of function, this project sought to improve the most simple of the components of the prosthetic system, the socket. These are often fabricated based on a volumetric cast of the residual limb, without much insight into the underlying anatomy. They are then fabricated using a wet lay-up infusion, using for raw materials, braided fabric tubes for the reinforcing fabric. The fabrication method takes a large amount of skilled labor, which may be better invested in patient care and more intensive rehabilitation techniques. Further, the method fails to control several key variables which determine the strength of the socket. As a result, and in order to prevent catastrophic failure in the socket, the structure is commonly ‘over-built,’ increasing weight for the system.

The grand design of this project was to address the fabrication method, utilizing instead, braiding, which is well established in the composite industry. The technique is known to produce very good strength to weight ratios, by increasing the fiber volume fraction in the components produced. Braiding can be used to create a number of different properties, but in order to meet the requirements of a design, a key question must be first answered. What structural properties are required? If we can make a structure with gradient properties, where would stiff sections belong, and where would more compliant sections be positioned?

The answers from the prosthetic industry were lacking, which is to say, the community did not consider their fabrication methods to be an area of need, nor did they see the need for more understanding of the underlying anatomy, for one main reason; they are able to provide excellent patient care without such things. The state of the practice is to design the socket based upon patient feedback, and the use of transparent ‘check’ sockets, and on gait analysis.

This project envisioned a different way. The patient’s anatomy can be studied through various medical imaging techniques. The exact positions of all of the various tissues (muscles, fat, bone, ligaments, vascular structures, neural structures, etc.) can be determined. This can be coupled with known stress-strain relationships for the tissues, allowing a complete model of the physical response of the residual limb. The goal was to use this tool to virtually design a socket for a patient, using finite element analysis to determine the load transfer paths that a given socket design would impose on the soft tissues, allowing a predictive analysis of the comfort of that design. In addition to providing patient care, a tool such as this could also allow for 'virtual innovation,' the testing of very novel socket designs without ever risking a patient's well-being.

In order to inform such a model, an additional tool must be brought to the field. The model requires data for input and for assessment of its predictions. One of the few ways we can verify the predictions of the model is at the surface of the residual limb. This project sought to use a polymer-based pressure measuring material to supply a high-resolution, 3-dimensional map of the pressures experienced at the surface of the residual limb.

In the course of preparing the project, and discussing worthwhile activities with stakeholders, additional needs were brought up. One of these was the desire to change a socket's fit after fabrication. This commonly arises as a need, because the human body is a dynamic system, and the residual limb more dynamic than healthy limbs, which continues to change volume in response to muscle atrophy, or abnormal bone growth. The community has some techniques for allowing such changes to the socket shape, including grinding away the composite in local areas and the inclusion of non-structural features specifically for removal at later times. When viewed from the viewpoint of a composite structure, both of these techniques have negative consequences on the socket structure; the former requires the socket to be either overbuilt from the beginning, or fatally compromised structurally, by the reduction in the composite structure, and the later adds parasitic weight to the structure specifically to allow later modification. In order to investigate alternatives, materials which have demonstrated alterability after fabrication were investigated. These would allow adjustment to the socket fit at later points in time, using techniques familiar to practitioners, without adding parasitic weight to the system.

A second area of need that came to light was the need to address overheating issues in the residual limb. When a patient's residual limb is covered by the prosthetic system, including a viscoelastic liner, the limb is robbed of all natural mechanisms for regulating temperature. No air flow is permitted, and the evaporation of sweat is repressed. This results in overheating, which is itself a major comfort issue which can limit prosthetic system use. The problem is exacerbated by the effect it has on the socket fit caused through overheating. The accumulation of sweat in the prosthetic system affects the system by acting as a lubricant, allowing more movement than desirable between the residual limb and the socket. Further, the generation of sweat by the residual limb is accompanied by local decrease of tissue volume, which further affects fit. What is required is some method of increasing heat removal from the system. A demonstration of such a system is reported here.

Objectives

The objective of this project was to dramatically improve the quality and comfort of sockets for lower-extremity prosthetic systems by shifting away from the current experience-based design and production paradigm. This project intended to allow intelligent design decisions for the composite socket, informed by both load requirements and soft tissue reactions.

An accompanying objective was to produce sockets at reduced costs, reduced labor inputs, and increased strength, in order to allow resources to be focused on patient care, more advanced terminal devices, and the latest rehabilitation techniques.

Another objective of this project was to implement resins developed in other areas into the field of prosthetics to enable local modifications of the composite structure.

The final objective of this project was to demonstrate that an active cooling system could be added to the prosthetic system and provide relief to overheating of the residual limb.

Approach

Task 1: Reconfigurable Sockets pursued two competitive technologies. One was from Clemson University, and focused on Diels-Alder chemistry, and the formation of a resin with cross-link bonds which could be broken and reformed through the application of heat. The second was the application of shape memory composite resins from Composite Technologies Development (CTD). These two technologies were both shown to have promise in this area. The materials developed by Clemson, while able to meet most of the key metrics for the application, faced a long road to scale up sufficiently to impact the problem, and so were not pursued further. The materials from CTD are already mature from a manufacturing readiness level, and so prototypes of sockets which were capable of reconfiguring were fabricated and evaluated.

Task 2: Medical Imaging and Modeling made use of a small patient population to gather MRI data from. This required careful manipulation of the patient's residual limb, to insure that the gathered data represented the state of the limb when confined to a relevant socket shape, and not the state of the limb when subjected to unconstrained gravity effects in a prone position (the position of the patient during the MRI). This also required optimization of the MRI collection, in order to provide a coherent data set which could be easily segmented into various tissue types. Only after this can the modeling effort be started, allowing analysis of sockets during donning, static standing, and single limb support.

Task 3: 3D Pressure Mapping used a material previously developed which is based on a polymer with carbon black fillers which changes the surface resistivity (as opposed to the bulk resistivity) in response to changes in applied pressure. In order to allow measurement of discrete points, areas of filled polymer needed to be seamlessly integrated with areas of neat polymer in a way that would allow the combination to be thermally deformed without creating flaws. Further, the system needed a way to measure each of the points at high temporal resolution and with good calibration.

Task 4: Automated Fabrication started from a firm belief that braiding could easily produce sockets, and worked to prove that point. A large portion of the effort was invested in quickly and easily fabricating molds which can be used in conjunction with the braiding technique. Several methods and materials were pursued. In parallel, the team optimized the braiding unit for use in the prosthetic environment and investigated ways in infusing composites with appropriate resins and producing acceptable sockets.

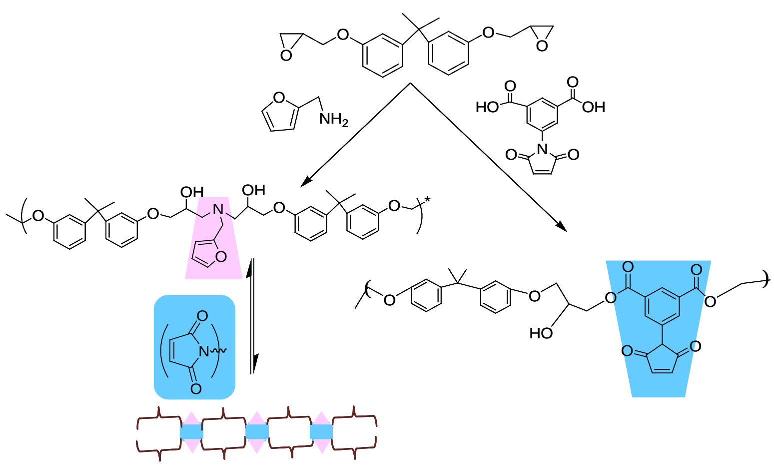
Task 6: Active Cooling Liner started with a well-established technology which was based upon a regulated flow to provide a set amount of cooling for a user's torso. In order to demonstrate this technology in the prosthetic environment, the system was modified to provide a smaller flow rate of liquid carbon dioxide. This was tested on the bench top to determine if the cooling levels achieved would be able to provide cooling effect through the insulation provided by liners currently used as part of the prosthetic system.

Results and discussion

Task 1: Reconfigurable Sockets

Clemson University explored several chemistries with 'self-healing properties' which were based on Diels-Alder reactions. Diels-Alder reactions are a broad class of organic chemical reactions in which two compounds join together in such a way as to form a new cyclic compound at their joint. This requires that the reaction sites have certain functional groups which contain a great amount of electrons, which are also able to participate in the reaction to form the new bonds required to form the new cyclic group. This reaction was exploited to form self-healing polymers by allowing the cross linking between polymer chains to be formed by Diels-Alder reactions because this reaction is relatively easy to drive in the reverse direction by the application of temperature. This allows the cross-links to be broken by the application of temperature, which results in increased molecular movement, filling in scratches (self-healing), or allowing the repositioning of fibers within the polymer (reconfiguration).

Clemson investigated several plausible chemistries for this purpose. One was a modified epoxy containing a furan moiety which was combined with commercially available bismalimides and maleimides, which showed crosslinks formed at 55 ^{o}C and the breaking of crosslinks at 130 ^{o}C, a relevant temperature range. Composites made using carbon fiber and this resin system demonstrated a heat-activated state in which reconfiguration was possible, and that the 'new' state would be retained when the sample was cooled to room temperature.



Cross-linked Epoxy

Figure 1: Reaction scheme for modifying commercially available epoxy with furan and maleimides.

The modification of commercially available epoxies achieved many of the program goals, but the resins had relatively high viscosity, making them difficult to process into high-quality composites. The system was therefore modified using various viscosity modifiers with epoxy end groups, such as aliphatic epoxies, and amine groups such as aniline and dodecyl amine.

These modifiers became part of the matrix upon curing, and decreased the viscosity of the resin during wet out, while maintaining the reversible crosslinking behavior.

In limited testing, the composites formed with the unmodified and modified resins showed remarkably stable mechanical properties after repeated healing cycles, meant to test the ability of the system to maintain strength through an adjustment of the socket. This is consistent with the findings of other researchers, where composites have shown 100% retention of mechanical properties after up to seven thermal cycles.

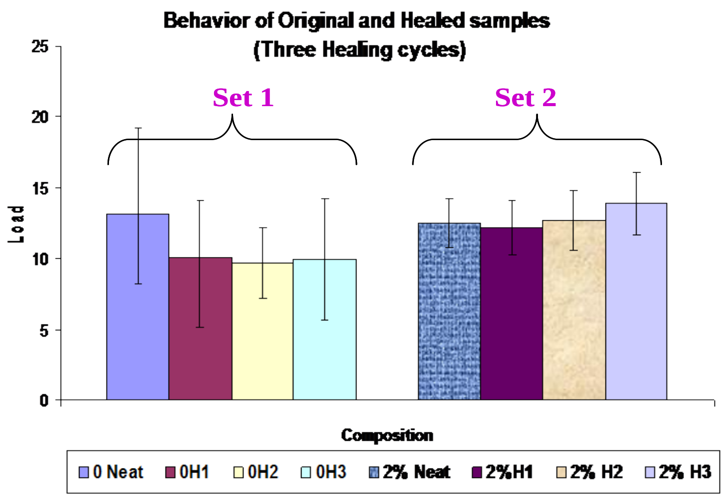


Figure 2: Epoxy Resin (Set-1), Modified Epoxy Resin (Set-2). Subset 1, Subset 2, 3 & 4 of each resin represents the original, first, second and third healing cycles of composite.

A third option explored was the use of terpolymers based on furfuryl methacrylate. Two options were successful in demonstrating the reversible cross linking behavior. These were polymerizations of furfuryl methacrylate, methylmethacrylate, and methacrylate, and polymerizations of acrylonitrile, furfurylmethacrylate, and styrene. These options were explored as lower cost alternatives to those discussed above.

Whereas Clemson University was focused primarily on the optimization of materials, Composite Technology Development (CTD) focused more on the application of their existing materials to the prosthetic socket. CTD's work to demonstrate the feasibility of applying TEMBO® Shape Memory Polymers showed that the resins and foams could allow a reconfigurable socket. The materials are well suited to this environment, having a glass transition temperature which allows a practitioner to fabricate a socket using familiar techniques and modify the socket with common tools (heat gun).

It was determined during the program that local reconfiguration requires more than the use of materials which can be reconfigured. This is simply because the woven nature of the composite fabric commonly used prevents changes in a local area; the fabric is 'locked' into place, and even full compliance in a local area may not be sufficient to allow the desired reconfiguration to be

accomplished. Because of this 'locked in' nature, other measures are required to allow sockets to be truly 'reconfigurable.'
CTD investigated several methods which would allow effective reconfiguration. These include localized thinning of the socket, localized slitting of the socket, and incorporation of foams at selected locations.

Because thinning and slitting of the socket both involve the compromise of the sockets mechanical properties, they were rejected as possible routes. Foams, on the other hand, do not compromise the structure of the socket, and can accommodate both positive and negative volume changes in the residual limb. This is possible because the foam can be inserted into the socket layup in either an expanded or compressed state. Upon heating, all foams will tend toward the expanded state, but are extremely pliable. Compressed foams will expand, altering the socket nearby to accommodate negative volume changes in the residual limb (which are most common); expanded foams can be compressed by the application of small forces, altering the socket nearby to accommodate positive volume changes. This approach provided the maximum socket reconfiguration (12mm of localized shape change).

Prototypes of reconfigurable sockets were fabricated and delivered to WRAMC, CFI, and NMCSD. They were well received.

Task 2: Medical Imaging and Modeling

Collection of the MRI data from the patient population was accomplished first. In order to present the same anatomical configuration of the residual limb in the standing, loaded position to the MRI taken in the prone position. Previous researchers have accomplished this by using a plaster 'containment shell' to constrain the residual limb throughout the scanning process. This prevents the residual limb from conforming to the force of gravity acting in a new direction. In order to apply a similar load to the forces applied to the residual limb during use, a belt or strap attached to the torso was used.

Figure 3: Containment shell and belting system

MRI is a volumetric imaging technique based on the excitation of hydrogen in water bearing tissues. However, a single tissue type will not return a constant signal throughout the imaging volume. This greatly complicates the segmentation of the scan data into various tissue types.

Further complications regarding the scanning parameters required to provide the most straightforward reconstruction of the data. The optimum protocol for trans-tibial amputations used a GE Medical Systems Sigma HDxt 3.0 Tesla MRI, conducted in the sagittal plane with a 28.0-30.0 cm field of view, and 1.6 mm slice thickness, with no overlap. An optimum set of conditions for the trans-femoral amputations was not found, and each patient was different. However, a recent innovation from GE, referred to as the IDEAL algorithm, provided the best images for modeling purposes.

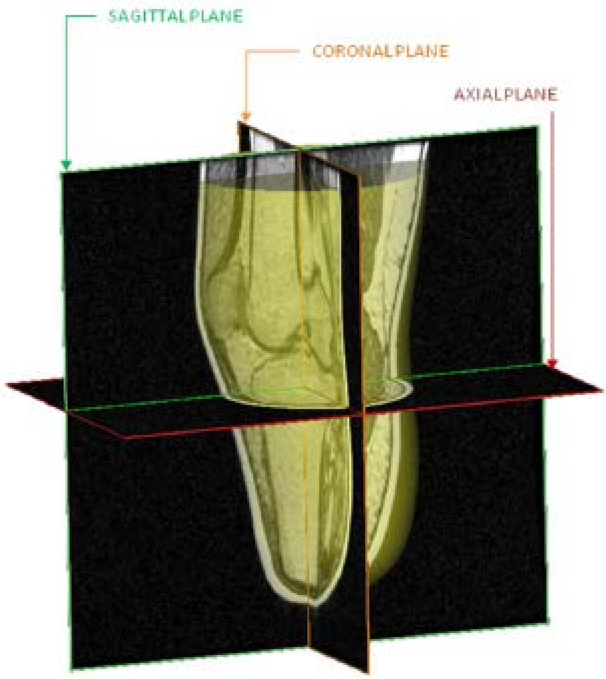


Figure 4: Representative MRI scan data

Segmentation of the MRI data is a difficult, laborious process, mainly due to two factors. First, adjacent tissue types are not easily distinguished by MRI in most cases, because adjacent tissue types commonly have similar water levels. Second, each tissue types will return a range of signal strengths (interpreted as gray-scale values by the MRI) throughout the imaging volume. In practice, the input of an experienced modeler cannot be removed from the process at this time.

The MRI data serves as the starting shape for the residual limb. Modifications are made to the model according to the state of the art practices of the prosthetics field; these are done to apply loads to areas which are best suited to carry it. With some accommodations made for the limitations of the various software packages which must be used, these can be done while visualizing the underlying anatomy of the patient.

Figure 5: Highlighted areas to be modified for an effective socket design, with patient anatomy present to inform decisions

The modeler then assigns the relationships between the various anatomical tissues, as appropriate. Some tissues slide past each other at their interfaces, and some are fixed. The various tissue types are then assigned properties, and are assumed to be isotropic and homogeneous. With further manipulation, the virtual socket can be applied to the model of the anatomy in a variety of loading states. Two were analyzed; donning, when the socket is only put on the limb and no load applied, and static standing, in which the body weight is applied to the residual limb. It was shown that the model can be used to analyze the pressure distribution on the residual limb, which demonstrates the major function of the gel liner. It also allows access to information never before seen. This includes the loading state of internal anatomical features, such as the external pressure distribution on the patella tendon, a feature which is considered capable of carrying load, and the internal tensile stresses of the same.

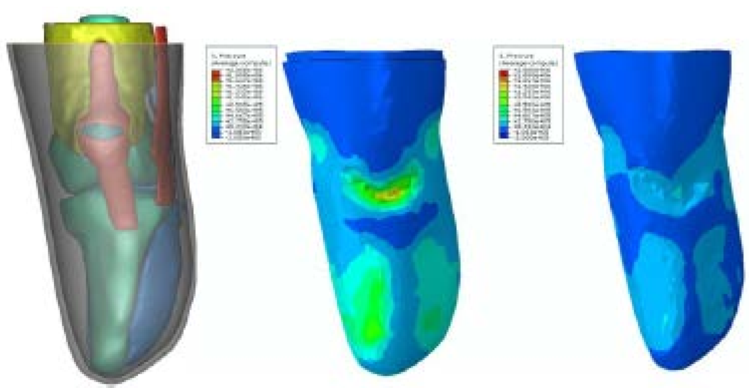


Figure 6: A visual demonstration of the function of the gel liner. The middle image shows the pressures on the surface of the gel liner, and the image on the right shows the pressures exerted on the skin, under static standing loads.

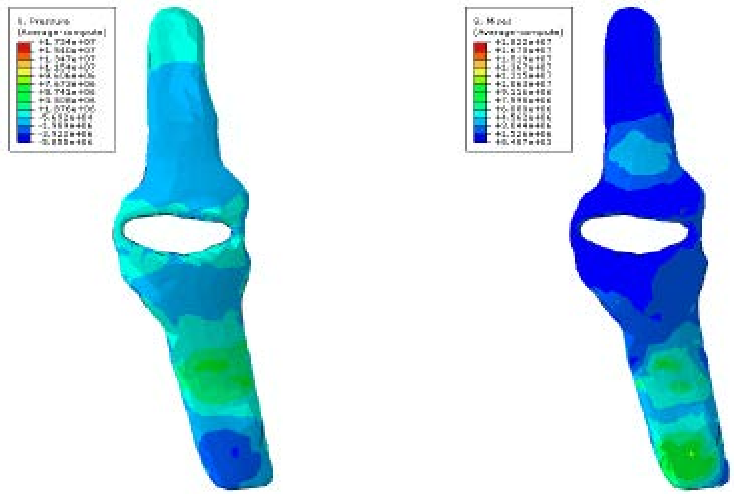


Figure 7: Comparison of the external pressure (left image) and the internal tensile load (right image) predicted for a patient wearing a patella tendon bearing socket design under static, standing loads.

In a way, this feature of the model perfectly illustrates the difficulty of this task. The model is capable of making predictions, but has no method of assessing the quality of these predictions. Without a method for assessing the output of these models, there is no way to improve them or determine their utility. This is the limitation at present. There is no method for assessing the accuracy of the predictions made, either on internal anatomy (illustrated by the images of the patella tendon above), or on the surface pressures (illustrated by the images of the residual limb).

In addition to the difficulty in confirming the predictions made by the models, there are a number of additional issues. One is that the tissue properties used by the model are garnered from healthy tissue. These may or may not be applicable to the tissues of a given patient, whose residual limb cannot be considered to be ‘healthy’ in the same way other limbs are. Finally, the skill sets required to accomplish this type of modeling rarely exist in the same individual, and it is unlikely that the modeling work will be able to replace the skill set that a trained prosthetist can bring to the process.

Task 3: 3D Pressure Mapping

The filled material had been previously developed. In order to make a pressure map, areas of the filled material had to be combined with areas of unfilled material. This proved difficult. Pressure molding of various shapes proved ineffective; the active regions either smeared unacceptably or the joint between the disparate regions was unacceptably weak during thermoforming events. The solution was to form a solid rod, made up of alternating discs of neat and filled polymers. These were compressed under heat, forming a strong, durable bond between the two materials. The rod was then put onto a lathe machine, allowing a thin sheet, with stripes of alternating materials, to be cut from the rod. The thin sheets were able to survive the thermoforming process and function as sensors.

With that accomplished, the system development focused on computing algorithms to continually monitor each sensor site. With the striped sheets, the system relied on two such sheets, with stripes oriented perpendicularly. Each intersection formed a sensor site. However, measuring each of these sites would require separate measurements on each of the sheets. With roughly 250 individual sensor sites available, the number of electrical measurements was a challenge for the system. The measurement of the sites limits the temporal resolution of the system. Further, the calibration of the system formed a significant challenge during the program.

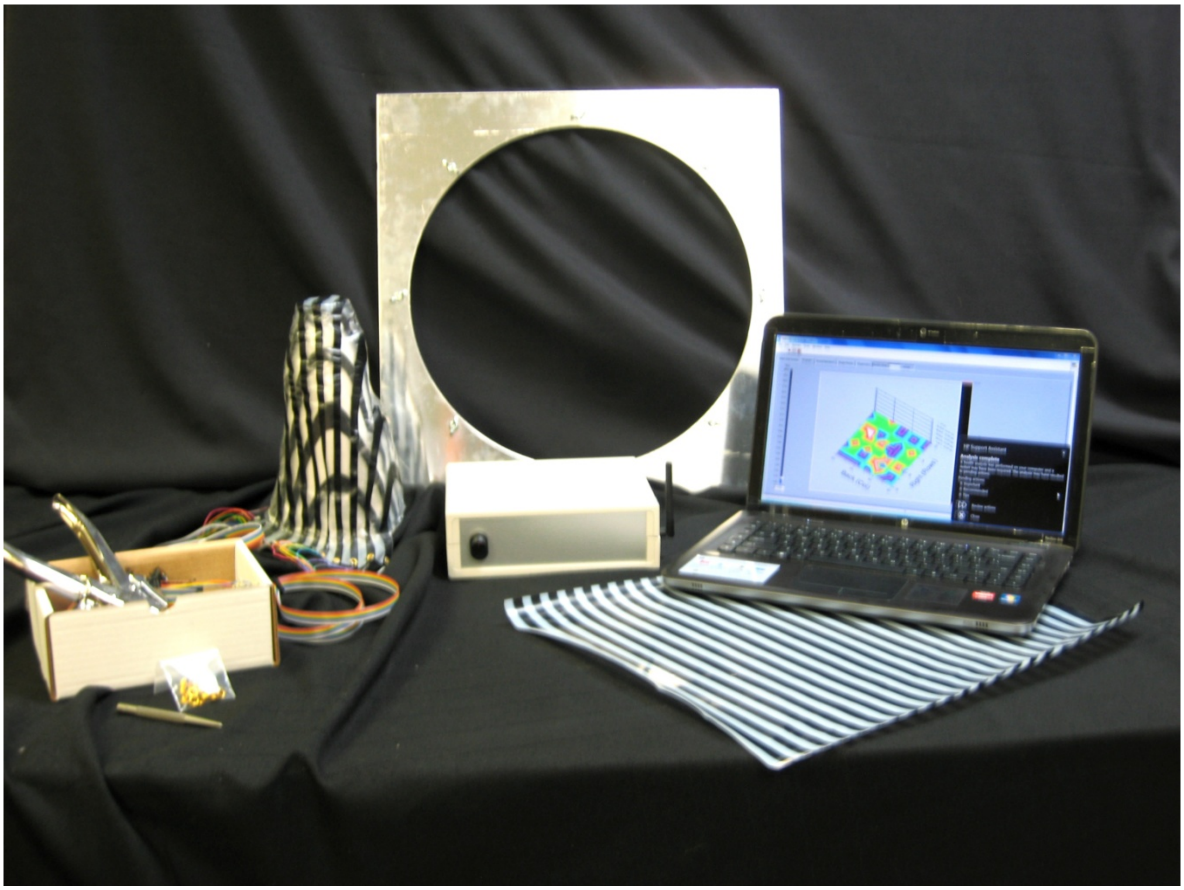


Figure 8: Picture of the system as developed during the program.

Task 4: Automated Fabrication

Mentis Sciences originally envisioned the use of braiding to create sockets, and they were convinced from the beginning that this was feasible. In order to have the maximum impact, not only were sockets to be fabricated, but they were to be superior products both mechanically and economically.

In order to accomplish this, one of the most important cost factors which needed addressing was the cost of the male mold. Prosthetists have been very comfortable over the years using plaster, but the use of plaster to make sockets efficiently and cost effectively would be implausible.

Mentis investigated alternatives such as Aquacore, a washout material designed for the composites industry to make tooling from. Mentis determined a method to use Aquacore, which involved machining blanks via CNC, followed by coating the mold to prevent resin infusion into the mold. Mentis also attempted to use plaster combined with CNC machining, however, these molds did not survive the machining process, due to the brittle nature of the material. Finally, Mentis investigated a machinable wax. This brought many advantages; it was machinable easily and quickly, was easily removed from the finished part, and could be collected and reused, addressing the cost of the material. The machinable wax proved to be a major cost savings over traditional methods. Others in the prosthetics industry use foam blocks; these may also be feasible, but were not investigated during this program.

In parallel, Mentis set about assembling a custom braider for use in the prosthetics environment. It was based on a commercially available, 64 carrier Wardwell braider, combined with a custom designed and built gantry system. The system also included a protective shroud, which made the system safer and contained dust from the system. The controls for the system, which allowed for user control over the process, were mounted to a swing arm, allowing quick and easy control over the speed of the braider and gantry.

In addition to the braiding process, socket fabrication demands the infusion of resin into the part. This can be accomplished in two ways. The first was to add the resin in between braiding of the fabric layers onto the mold. The second was to put all the fabric onto the mold and infuse the resin in the vertical position, as traditionally done. In either case, because the braider applies tension to the composite fabric as it is placed onto the mold, superior compression and compaction occurs between layers. This means the same amount of reinforcement fabric occupies less space, and then takes less resin to fill in the voids in that space. This in-situ debulking of the part reduces the resin required by approximately 50%. This has a huge impact on the strength-to-weight ratio of the socket, because the mechanical properties are mainly determined by the fibers, and the optimum strength is found when the resin content is kept to a minimum.

In the end, the second method of infusing the resin was chosen, because this results in the smoothest exterior surface for the composite. This was an appearance issue for the socket.

The braiding technique was transitioned to two central fabrication locations, which were trained on its use.

Task 6: Active Cooling Liner

The first thing that must be done in repurposing the cooling system for use in the prosthetics environment is to determine the cooling level that is desired. After analyzing the literature in a number of different ways, it was determined that the goal would be 5-7 Watts of cooling. This was arrived by analyzing the temperature rise reported by amputees in their prosthetic system (1.7 ^{o}C after 10 minutes of walking), and the metabolic rate of the average body during similar activity levels, apportioned by the body area of the residual limb.

With this goal, additional requirements for the system were detailed. These included low noise generation, minimal comfort impact caused by the cooling lines, refillable coolant supply, to be mounted to the user's belt. It was determined that, for the needs of demonstrating the technology, the cooling lines would be sewn onto a sock, and that sock would be sandwiched in between two commercially available liners. The arrangement was required to allow radial and axial stretching, expected deformation directions for the liner during use, and survive 1200 bending cycles.

The majority of the effort was to determine a way of reducing the coolant flow rate to meet the relatively low cooling requirement. At the end of the period of performance, we were unable to achieve a flow low enough to supply only the desired 5-7 Watt cooling while maintaining stable flow.

Alternative methods for restricting the flow of liquid carbon dioxide may be required to provide a steady flow of liquid carbon dioxide and achieve the cooling rate projected. However, it may be worth noting that higher cooling levels may also be both clinically effective and perhaps even desirable; this must be optimized in the future, as the lower flows will make a given supply of liquid carbon dioxide last longer.

The major finding of the work was that the viscoelastic gel liner presented only a small barrier to the heat transfer of the system. The insulating effect of the liner is a primary driver of the overheating problem experienced by patients. However, the driving force for heat transfer present at room temperature is extremely small, on the order of 20 ^{o}F, compared to the driving force for the active cooling liner, which can be as high as 80 ^{o}F. With this larger driving force for heat exchange, a steady state temperature gradient can be established, which is certainly affected by the insulating effect of the liner, but is not rendered ineffective by its presence. This was tested using a bench top test in which water was used as a flowing medium for heat exchange, which measured the heat transfer from the cooling lines through the liner accomplished by the system. The results show that relevant heat transfer rates can be achieved through the liner.

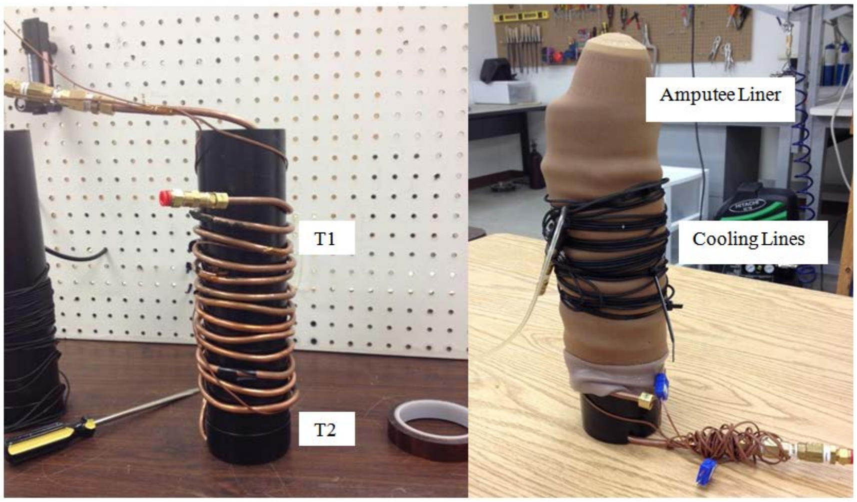


Figure 9: Water flow system used to establish the thermal resistance presented by the liner to the active cooling system.

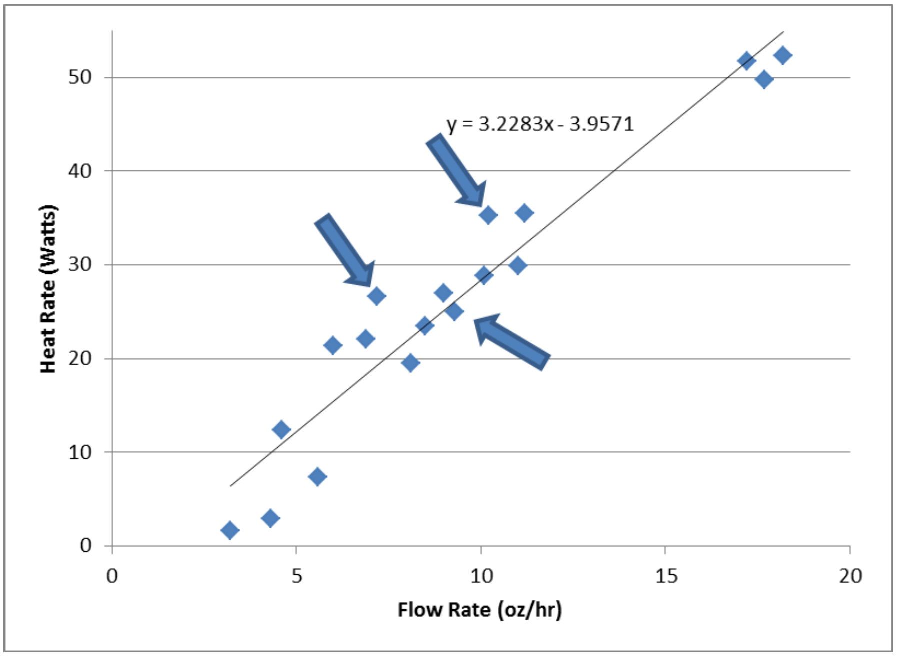


Figure 10: Measured heat exchange rate as a function of liquid carbon dioxide flow rate, when measured through the liner material.

Benefits Analysis

The resins used in Task 1: Reconfigurable sockets displayed suitable amounts of adjustability and retained strength suitably through the adjustment cycles. However, these resins were considerably more expensive than the common prosthetics resins.

The 3D Pressure Mapping system developed in Task 3 brought a new capability to the field, and development has continued on it after the conclusion of the program's investment in it.

The braiding technology was successful in producing custom composite sockets at a reduced cost **(~34% reduced cost)**, and are capable of producing stronger and more consistent prosthetic sockets. The technology allows for the fabrication of a truly engineered product, and is expected to enable the development of standards on the fabrication of sockets. Further, this technique is expected to help facilitate the design and production of emerging paradigms for comfortable sockets. The skilled labor required for fabrication is reduced **(~50% reduced labor input)**, as is the waste in production. Finally, the produced sockets are roughly **50% lighter** for the same strength as traditionally fabricated products, while maintaining all other relevant criteria, including aesthetic. This will allow a focus of limited resources (both time and funding) on providing care directly to the wounded while delivering superior components for prosthetic and orthotic systems.

The active cooling system demonstrated that such a technology can provide cooling through the thermal barrier of the liner. Further development is required to build on this initial proof of concept.

Task 1: Conformable Resins									
Parameter	Baseline Value	Requirement Threshold Value	Requirement Objective Value	How to Measure	Date to be Achieved	Achievement Value	Achievement Date	How Demonstrated	How Demonstrated
Conformability	0	2 mm	4mm	Direct Measurement	March-09	4 mm	March-09	CTD Socket Deliverables	CTD Socket Deliverables
Retained Strength	0	90%	95%	Direct Measurement	August-09	95%	July-09	Clemson 3-pt bending test	Clemson 3-pt bending test
Resin Cost	$60.00	130%	120%	Project Estimates	August-09	~300%	August-10	Clemson Price Quote	Clemson Price Quote
Task 4: Automated Manufacturing									
Parameter	Baseline Value	Requirement Threshold Value	Requirement Objective Value	How to Measure	Date to be Achieved	Achievement Value	Achievement Date	How Demonstrated	How Demonstrated
Cost (excluding non-recurring costs)	$162.73	$155	$146	Project Estimates	Dec-10	$101.13	Nov-10	Cost Estimates	Cost Estimates
Labor Time	4	2	1	Project Estimates	Dec-11	2	Nov-10	Cost Estimates	Cost Estimates

Implementation Status

Task 3: 3D Pressure Mapping

The high resolution pressure mapping system was commercially launched (Zebra^{TM} Sensors) in September 2010; this system allows for the measurement of the pressures that the residual limb experiences, and is capable of making detailed measurements during all major phases of a patient's activity (sitting, standing, walking, and running). This system has been purchased several early adopters for use in clinical and research settings.

Task 4: Automated Fabrication

This task has resulted in significant transition of the braiding technology to the industrial base serving the prosthetics community. This technology allows for fabrication of sockets at approximately **34% reduced costs**, and with approximately **half of the skilled labor input**. An industrial partner (Friddles Orthopedic Appliances, FOA) has agreed to serve as a distributer for the braider systems assembled by Mentis Sciences, and two central fabrication facilities (FOA; O & P 1) have already purchased braiders for producing components. These sites are now servicing all branches of the government, including both Defense and Veteran's Administration; further, these facilities are also servicing the civilian population and elite Paralympic athletes as well.

These technologies were proven out for prosthetic sockets, but have application to other components applicable to the field, including orthotics. Transition to the industrial base is allowing innovation utilizing these advanced techniques to develop new products for the field, including facilitating the design and production of emerging paradigms for comfortable sockets.

Task 1: Reconfigurable Sockets

The shape memory foams and resins are currently available for government purchase for use in fabricating sockets. Prototypes, which were positively received, were delivered to Walter Reed Army Medical Center, the Center for the Intrepid, and Navy Medical Center San Diego.

Task 6: Active Cooling Liner

The demonstration of this technology has only recently been accomplished. SCRA, in partnership with Porticos, is investigating transition opportunities, which are expected to be significant.